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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,455	04/08/2004	Myles S. Douglas	ENDOLOG.054A	7278

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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER

TYSON, MELANIE RUANO

ART UNIT	PAPER NUMBER
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3731

NOTIFICATION DATE	DELIVERY MODE
08/07/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
eOAPilot@kmob.com

Office Action Summary	Application No.	Applicant(s)
	10/820,455	DOUGLAS ET AL.
	Examiner Melanie Tyson	Art Unit 3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 10 April 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-44 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-44 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/10/07</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

This action is in response to Applicant's amendment received on 10 April 2007.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 19, and 31-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 recites the new limitation "a tubular ePTFE sheath on the wire support, the tubular sheath being configured to inhibit the formation of a viable neointimal layer on the luminal surface of the sheath *along the sheath's entire axial length*," claim 31 recites the new limitation "*along the tubular ePTFE layer's axial length*," and 32 recites the new limitation "*along the layer's axial dimension*." The added limitations include subject matter not described in the application as filed. Applicant simply disclosed a "sheath being configured to inhibit the formation of a viable neointimal layer on the luminal surface of the sheath" (see paragraph 15 of the specification), which merely indicates a portion thereof.

Claim 19 recites the new limitation "while controlling cellular ingrowth through the wall of the tubular configuration to substantially prevent the formation of a thin, viable

neointima over the inner surface thereof *from the proximal end to the distal end,*" claim 33 recites the new limitation "*from the proximal end to the distal end,*" and claim 34 recites the new limitation "*at the proximal end.*" The added limitations include subject matter not described in the application as filed. Applicant simply disclosed a "sheath being configured to inhibit the formation of a viable neointimal layer on the luminal surface of the sheath" (see paragraph 15 of the specification), which merely indicates a portion thereof.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant recites the limitation "the membrane having a membrane proximal end region and a membrane distal end region and configured to *inhibit* cellular growth through the membrane *which would be sufficient to enable* the formation of a thin, viable neointimal layer on the luminal surface of the membrane at least at the membrane proximal and distal regions." It is unclear as to how *inhibiting* cellular growth on the membrane *enables the formation* of a neointimal layer on the membrane.

Claim Rejections - 35 USC § 102/§ 103

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-44 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Shaolian et al. (6,197,049).

Shaolian discloses a stent graft comprising all the configurations as claimed (see column 6-21). However, in the alternative, it would have been obvious to one of ordinary skill in the art at the time the invention was made to configure the sheath to inhibit cellular growth, thus inhibiting the formation of a viable neointimal layer on the luminal surface of the sheath along the sheath's entire axial length, from the proximal end to the distal end, or at least a sheath's proximal or distal end regions.

Shaolian discloses the porosity characteristics of the sheath (44) may be either homogeneous throughout the axial length of the prosthesis or may vary according to the

axial position along the prosthesis (for example, see column 6, lines 49-52). Shaolian teaches examples in which the sheath (44) is nonporous or provided with pores of relatively low porosity in areas where anchoring is less of an issue, and thus does not require endothelial growth (for example, see column 6, lines 61-67). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to configure the sheath to inhibit cellular growth along the luminal surface of the sheath's entire axial length, from the proximal end to the distal end, or at least a sheath's proximal or distal end regions in applications that do not require anchoring along the sheath's entire axial length, and one desires to do so.

Response to Arguments

Applicant's arguments filed 10 April 2007 have been fully considered but they are not persuasive. Applicant argues primarily that the applied prior art fails to teach or suggest all of the claim language of amended claims 1, 18, 19, and 31-34. Examiner respectfully disagrees.

Applicant argues that the Shaolian patent fails to teach or suggest inhibiting the formation of a neointima along a *sheath's entire axial length, from a sheath's proximal end to its distal end, or at least at a sheath's proximal or distal end regions*. However, Shaolian discloses that in the central zone (57) of the prosthesis (42), the sheath (44) may either be nonporous, or provided with pores of relatively low porosity (for example, see column 6, lines 65-67). Shaolian further discloses the sheath (44) is positioned on the central zone (57) such that it spans the aneurysm to be treated, leaving the proximal zone (55) and distal zone (59) exposed (for example, see column 7, lines 1-10).

Therefore, the sheath's entire axial length is nonporous, or provided with low porosity, and thus the sheath is *configured* to inhibit cellular growth therethrough, thus *configured* to inhibit the formation of a viable neointimal layer on the luminal surface of the sheath along the sheath's entire axial length, from a sheath's proximal end to its distal end, or at least at a sheath's proximal or distal end regions.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571) 272-9062. The examiner can normally be reached on Monday through Thursday 9-5:30, Fridays 8-4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson
July 25, 2007

MT

Tan-uyen Ho
(JACKIE) TAN-UYEN HO
SUPERVISORY PATENT EXAMINER

8/2/07